

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on scientific disputes between the Center for Devices and Radiological Health and sponsors, applicants, and manufacturers.

Date and Time: The meeting, which is rescheduled from June 4, 2001, will be held on September 6, 2001, from 8 a.m. to 6 p.m.

Location: Marriott, Salons E, F, and G, 9751 Washingtonian Blvd., Gaithersburg, MD.

Contact: Les Weinstein, Center for Devices and Radiological Health (HFZ-5), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-6220, ext. 119, FAX 301-827-2565, lsw@cdrh.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 10232. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss, make recommendations, and vote regarding a scientific dispute between the agency and Lifecore Biomedical, Inc., related to the approvability of a premarket approval application for Intergel, an adhesion prevention solution for use in gynecologic

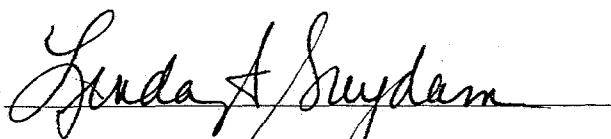
pelvic surgery. Background information and questions for the committee will be available to the public on September 5, 2001, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 4, 2001. Oral presentations from the public will be scheduled between approximately 8 a.m. and 8:30 a.m. on September 6, 2001. Near the end of the committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the dispute before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 4, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee meeting. Because the agency believes that there is some urgency to bring this issue to public discussion and qualified members of the Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: 8/16/01
August 16, 2001.



Linda A. Suydam,
Senior Associate Commissioner.

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